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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,953	10/03/2000	Hiroshi Kubota	320727.50401.	7343

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09/04/2003

KATTEN MUCHIN ZAVIS
525 West Monroe Street
Suite 600
Chicago, IL 60661-3693

EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

20

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/678,953

Applicant(s)

KUBOTA ET AL.

Examiner

Thái-An N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Continuation of 2. NOTE: Applicants' Amendment to the claims raises new considerations with regard to 112, 2nd ¶ and search, with the recitation of "single-cell". See Claim 1, for example..

Continuation of 5. does NOT place the application in condition for allowance because: Applicants argue that the claims are not anticipated by Sargiacomo because Sargiacomo does not disclose each and every element of the claims. Applicants argue that Sargiacomo teaches multi-size spherical hepatic units, and that they fail to teach the isolation of single-cell hepatic progenitors, but actually teaches away from single-cell culture methods. Applicants further argue that Sargiacomoo does not indicate that bipotent hepatic progenitors exist within the cultures as taught by Sargiacomo. See p. 10, 2nd of Applicants' Response. Applicants argue that Sargiacomo performed none of the tests taught by Applicants to identify the presence of the bipotent hepatic progenitor cells and there is no way to know whether such progenitors exist. Applicants argue that it is possible that 1) bipotent hepatic progenitors are present or 2) that they are not present in the teachings of Sargiacomo. Applicants submit that the teachings of Haruna, which are used as evidence that hepatic progenitors are present in fetal human liver, Applicants teach staining in sections of intact liver, not dissociated liver components. Accordingly, Applicants conclude that that application of the Haruna identification methods to the cultures of Sargiacomo would not yield the bipotent hepatic progenitor cells of the present invention.

Note that the amendment to the claims has not been entered. Applicants' arguments have been considered but are not found to be persuasive for reasons of record advanced in the prior Office action, pp. 3-5. Particularly, that the specification teaches the the compositions of bipotent hepatic progenitor cells of the claimed invention were obtained from human fetal livers, and as such, the claimed properties of the cells are inherent to the cells. As Sargiacomo's cells are disclosed to be isolated from human fetal livers, as are those cells claimed by the Applicant, they would reasonably be expected to have the same physical and biochemical properties.

With regard to the prior rejection under 112, 2nd ¶, with regard to the expression "capable of", the rejection is maintained for reasons of record advanced on pp. 2-3 of the prior Office action. Applicants argue that by amended the claim to recite, "when exposed to differentiation-inducing growth conditions" overcomes the prior rejection. The rejection is maintained because the amendment has not been entered. Furthermore, it is reiterated that the expression "capable of" encompasses things that could (or could not) occur. As such the expression describes a latent characteristic, which is unclear if the characteristic is obtained or even occurs.